

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Karin Golz-Berner et al.

Application No.: 10/520,562

Examiner: CHUI, Mei Ping

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Group Art Unit: 1616

Attorney Docket No.: 3975.039

Confirmation No.: 5263

For: ANTI-AGEING SKIN COSMETIC

DECLARATION OF CO-INVENTOR KARIN GOLZ-BERNER
UNDER 37 C.F.R. §1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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I, Karin Golz-Berner, declare as follows:

1. I am a co-inventor of the above-referenced U.S. Patent Application No. 10/520,562 entitled "Anti-Ageing Skin Cosmetic" (hereafter the '562 Application), and the subject matter described therein. I am also an inventor on at least 18 United States Patents, at least 19 U.S. Patent Publications, and more than one hundred patents and patent applications filed outside the United States.

2. From 1981 and 2008, I was involved in research and development in the cosmetic industry. From 1992 to 2008, I was employed by Coty International Group or a subsidiary thereof. During the period from 1992 to 2008, I served as the Director of Coty International's Creative Research and Development Center in Monaco.

3. I have reviewed the Office Action mailed April 1, 2009 (hereinafter "Office Action") and the Examiner's assertions therein, as well as the cited references. In the Office Action, claims 1-5 and 7 were rejected under 35 U.S.C. §103(a) as being

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unpatentable over Canadian Patent No. 2,335,149 issued to Golz-Berner *et al.* (hereinafter "Golz-Berner") in view of PCT No. WO 00/64472 issued to Murad, H. (hereinafter "Murad") and U.S. Patent No. 6,652,868 issued to Simon *et al.* (hereinafter "Simon"). The Office Action asserts that Golz-Berner discloses all elements of the claims with the exception of extracts from pomegranate, rosemary, figs and peeled musk melons. The Office Action then asserts that these ingredients can be found in the secondary references and that any additional differences are merely the result of judicious selection and optimization. I respectfully disagree, because the cited references fail to disclose several substantial claim elements and substantial unexpected results produced by the claimed anti-ageing cosmetic.

The subject matter of the claimed anti-ageing skin cosmetic as set forth in claim 1 is drawn to:

1. (original) An anti-ageing skin cosmetic comprising:
0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits;
0.1 to 3% by weight of an extract from pomegranate fruits;
0.001 to 0.5% by weight of a ground dry mixture of rosemary stems and leaves;
0.01 to 3% by weight of liposomes containing an extract from peeled musk melons;
0.1 to 5% by weight of liposomes containing a plankton extract containing the photolyase enzyme;
0.1 to 5% by weight of liposomes containing 0.1 to 0.5% by weight, in relation to the liposome weight, of a micrococcus lysate containing the UV-endonuclease enzyme; and
up to 100% by weight, other active substances, carrier substances, adjuvants or mixtures thereof, all percentages being relative to the cosmetic's total weight.

The claimed anti-ageing skin cosmetic unexpectedly produces enhanced reduction of fine wrinkles over other combinations of the claimed ingredients. In addition, the claimed anti-ageing skin cosmetic requires a ground, dry rosemary mixture and an extract from a mixture of fig leaves and fruits. The cited reference do not disclose or suggest

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either of these claimed features and do not disclose or suggest the claimed anti-ageing skin cosmetic including the claimed combination of ingredients.

The Office Action asserts that Murad discloses the claimed 0.001 to 0.5% by weight of ground, dry rosemary mixture. Murad is drawn to a composition that includes a fruit extract in a pharmaceutically acceptable carrier for treating dermatological disorders. Murad, Abstract. Murad discloses that *rosemary extract, i.e., an aromatic oil*, may be included in an amount ranging from 0.5-8 wt-%, preferably 0.7 to 7 wt-%. Murad, Page 16, ln. 28; Page 18, ln. 8-11.

In contrast to the aromatic rosemary extract of Murad, the claims are drawn to ground dry mixture of rosemary stems and leaves in an amount of 0.001 to 0.5 wt-% (claim 1) or 0.001 to 0.01 wt-% (claim 5). As explained in the Specification:

Rosemary (*Rosmarinus officinalis*) is not used in the known form of an extract or oil, but as a ground dry mixture of stems and leaves. *Such a mixture surprisingly has a high free-radical-scavenging activity and therefore a very high radical protection factor (RPF).*

Specification, Paragraph [0009].

As explained in the Specification, the claimed ground, dry rosemary mixture of stems and leaves have surprisingly high RPF values compared with the aromatic oil extract disclosed by Murad. Clearly, Murad fails to disclose both the claimed dry mixture of rosemary stems and leaves, as well as, the claimed amount of the dry rosemary mixture. It is the interaction of the claimed ingredients, including the dry rosemary mixture, in the claimed amounts that results in the unexpectedly superior anti-ageing effect, which is discussed in Section 4. Specification, Paragraph [0036]-[0039]. There is nothing in Murad or the other cited references that discloses or suggests using the claimed dry mixture of rosemary stems and leaves in the claimed amounts.

The Office Action asserts that Simon discloses the claimed 0.1-5% by weight of an extract from a mixture of fig leaves and fruits. Simon is drawn to a method of epidermal peeling in a human and production of a preparation for implementation of the method. In particular, the compositions disclosed by Simon include vegetable derived elements characterized by sufficient length and rigidity to enter into the horny layer of the

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skin and facilitate skin resurfacing. Simon, Abstract. In other words, the vegetable derived elements are coarse fibers that provide a pumice-like function.

Simon explains that it is possible to obtain satisfactory skin resurfacing using a multitude of vegetable derived elements of very small size, *i.e.*, 5 to 100 microns. Simon, Col. 2, ln. 29-36, 42-50 & 58-63. Simon discloses that the multitude of elements are preferably of vegetable origin and may include "the hairs that are present on the surface of *Ficus carica* leaves." Simon, Col. 3, ln. 7-17 & 28-33. The compositions disclosed in Simon contain 20 to 60 wt-%, preferably 30 to 40 wt-% of the elements of vegetable origin. Simon, Col. 5, ln. 37-43.

Taken as a whole, it is clear that Simon discloses including 20 to 60 wt-% of hairs from *Ficus carica* leaves in fiber form in order to provide a pumice-like effect. In contrast, the claims are drawn to compositions containing 0.1 to 5 wt-% of an extract from a mixture of fig leaves and fruits. Thus, the function and mechanism of any anti-ageing effect of the 20 to 60 wt-% *Ficus carica* leave hairs in Simon is completely different than the claimed 0.1 to 5 wt-% of an extract from a mixture of fig leaves and fruits. Simon provides no disclosure regarding any anti-ageing effect of the claimed extract as the hairs relevant to Simon serve a purely mechanical purpose, like the grit of sandpaper, rather than the chemical or biological function provided by the claimed active ingredients.

Furthermore, it is the interaction of the claimed ingredients, including the extract of fig leaves and fruits, in the claimed amounts that results in the unexpectedly superior anti-ageing effect. Specification, Paragraph [0036]-[0039]. There is nothing in Simon or the cited references to disclose or suggest using the claimed extract of fig leaves and fruits in the claimed amounts.

In fact, because Simon teaches the use of *Ficus carica* leave hairs to provide a mechanical pumice-like effect, Simon provides a strong teaching away from an extract of fig leaves and fruits in the claimed amounts. Clearly, an extract would not provide the mechanical pumice-like effect that is critical to Simon.

In summary, the claimed anti-ageing skin cosmetic exhibits a synergistically improved anti-ageing skin effect when the claimed ingredients are included with the

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claims amounts of (i) an extract of a mixture of fig leaves and fruits, and (ii) a ground dry mixture of rosemary stems and leaves, are present in the anti-ageing cosmetic. The cited references fail to disclose or suggest either of these feature in the claimed amounts or otherwise. In fact, the cited references teach away from the claimed (i) an extract of a mixture of fig leaves and fruits, and (ii) a ground dry mixture of rosemary stems and leaves. Accordingly, it is clear that the cited references fail to disclose or suggest each of the claimed elements.

4. In addition to the fact that the cited references fail to disclose or suggest the claimed combination of ingredients, the claimed anti-ageing skin cosmetic produces unexpected anti-ageing effects with respect to the elimination of wrinkles, *e.g.*, fine lines. As explained in the Specification:

The anti-ageing skin effect to be expected from the inventive anti-ageing skin cosmetic due to some of its constituents is by far exceeded by an overall synergetic effect. In addition, the cosmetic achieves an excellent moisture replenishment in the skin which could not be expected from the basic constituents alone.

Specification, Paragraph [0014].

With respect to the expected anti-ageing effect, Applicants note that the Golz-Berner reference is drawn to a cosmetic preparation with a high protection factor against free radicals. The Golz-Berner composition includes five "basic components" labeled (a) through (e). Golz-Berner, Page 2, ln. 26 – Page 3, ln. 11; Page 6, ln. 14-16. These basic components constituted the "association complex," which has a high radical protection factor. Golz-Berner, Page 13, ln. 35 – Page 14, ln. 15. For example, examples 1-6 include association complex compositions having radical protection factor (RPF) values for the basic components ranging from 1925 to 5600. Golz-Berner, Page 17, ln. 3 – Page 19, ln. 19.

From this it is clear that the compositions of Golz-Berner exhibited an RPF that exceeds most other skin care compositions. Thus, a substantial improvement in reduction of fine lines over Golz-Berner, such as that produced by the claimed anti-ageing skin cosmetic, is indeed an impressive and unexpected result.

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In order to quantitatively demonstrate this synergistic result, attention should be drawn to the unexpected reduction in fine lines produced by the compositions of Example 1 of the Specification and the data being submitted with this Declaration. The comparison of Example 1 to a control can be found in Example 3, which describes the results of consumer tests of two groups. The first group of consumers (Group 1) applied the claimed anti-ageing skin cosmetic of Example 1 to their face for four weeks. The second group of consumers (Control 1) applied the cosmetic of Example 1 without the rosemary powder or the pomegranate extract. Specification, Paragraphs [0036] and [0039]. The percentage of consumers experiencing a reduction in fine lines after 1, 2 and 3 weeks is summarized below for each of these anti-ageing skin cosmetics:

	Group 1	Control 1
After 1 week	76%	33%
After 2 weeks	81%	43%
After 3 weeks	83%	45%

Thus, it is clear that the combination of the claimed ingredients provides a substantially improved reduction in fine lines when compared to a composition that is identical except for the absence of the rosemary powder and pomegranate extract. Considering the fact that those consumers in the Control 1 group were utilizing the highly active composition disclosed in the Golz-Berner reference, this level of improvement was completely unexpected to me and my co-inventors.

In order to demonstrate the synergistic improvement in reduction of fine lines produced by the claimed anti-ageing skin cosmetics, I submit the following data obtained from a consumer study (Control 2) using an anti-ageing skin cosmetic containing only the rosemary powder and pomegranate extract from the Example 1 composition, *i.e.*, without the ingredients found in Control 1.

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The percentage of consumers experiencing a reduction in fine lines after 1, 2 and 3 weeks is summarized below for each of these anti-ageing skin cosmetics:

	Group 1	Control 1	Control 2
After 1 week	76%	33%	8%
After 2 weeks	81%	43%	17%
After 3 weeks	83%	45%	17%

Clearly, both Controls fall far short of the fine line reduction produced by the claimed anti-ageing skin cosmetic of Example 1. It should also be noted that, with the exception of the ingredients that were not included, the active ingredients and the amounts of the active ingredients used for Controls 1 and 2 were the same as those of Example 1. Thus, the combination of the active ingredients and amounts thereof used for Control 1 and Control 2 are the same as those in Group 1. In the absence of a synergistic relationship between the ingredients, it would be expected that the percentage of individuals experiencing a reduction in fine lines using the cosmetic of Example 1 would be equal to the sum of those experiencing a reduction in fine lines using the cosmetic of Control 1 and Control 2. For purposes of comparison, the percentage of consumers experiencing a reduction of fine lines after 1, 2 and 3 weeks for Group 1 is compared to the sum of those experiencing a reduction of fine lines for Control 1 and Control 2 in the table below:

	Group 1	Control 1 + Control 2
After 1 week	76%	41% (33% + 8%)
After 2 weeks	81%	50% (43% + 17%)
After 3 weeks	83%	52% (45% + 17%)

The reduction in fine lines is at least 31% for each of the three time periods. Clearly, there is a synergistic effect produced when each of the claimed ingredients is combined with the others. This synergistic effect simply is not present when the ingredients are not used together. Furthermore, the magnitude of the increased reduction

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in the presence of fine lines over the composition used in Control 1 is particularly impressive considering the RFP values reported in the Golz-Berner reference.

These results clearly demonstrate an unexpected, synergistic improvement in the reduction of fine lines when the claimed combination of ingredients is utilized.

Furthermore, there is nothing in the cited references, whether considered alone or in combination that discloses or suggests this unexpected synergistic result.

5. In conclusion, it is my opinion that the cited references neither disclose nor suggest the claimed anti-ageing skin cosmetic. In particular, the cited references fail to disclose or suggest at least the following claim elements:

- (i) an extract of a mixture of fig leaves and fruits,
- (ii) a ground dry mixture of rosemary stems and leaves, are present in the anti-ageing cosmetic, and
- (iii) the claimed amounts of each.

Furthermore, the claimed anti-ageing skin cosmetics unexpectedly produce a synergistically enhanced reduction in fine lines. This synergistic reduction in fine lines is substantially superior to the results produced by compositions found in my Golz-Berner reference, which exhibited extremely high RPF values. Because the base material exhibits such excellent RFP values, the substantial synergistically improved anti-ageing effect is even more unexpected.

6. I further state that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with my knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Monaco 1.7.2009
Date

Karin Golz-Berner, Ph.D.